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DOCKET NUMBER: 197330US0/hc

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF : Shuji MIYAGAWA, et al.

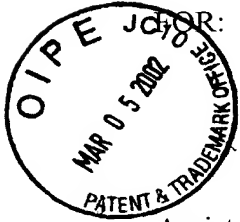
SERIAL NUMBER: 09/662,128

: GROUP: 1633

FILED: September 14, 2000

: EXAMINER: Celine QIAN

TITLE: MODIFIED CRE RECOMBINASE GENE FOR MAMMALS



LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith is the Japanese Office Action for the Examiner's consideration. The reference(s) cited therein have been received by the U.S. Patent and Trademark Office through an Information Disclosure Statement filed on December 5, 2000.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

A handwritten signature in cursive script, appearing to read "Norman F. Oblon".

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(Translation)

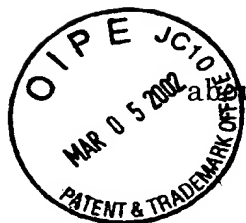
Mailed: June 13, 2000

NOTIFICATION OF REASONS FOR REJECTION

Patent Application No.: 264364/99

Examiner's Notice Date: June 2, 2000

Examiner: N. Honma



This application is rejected on the grounds stated below. Any opinion about the rejection must be filed within 60 DAYS of the mailing date hereof.

REASONS

1. The inventions of the claims mentioned below are unpatentable under Section 29 (2) of the Patent Law, as being such that the inventions could easily have been made by a person with ordinary skill in the art to which the invention pertains, on the basis of the invention described in the following publication(s) distributed in Japan or a foreign country prior to this application.
2. The invention of the claim mentioned below is unpatentable under the main provision of Section 29 (1) of the Patent Law.
3. The inventions of the claims mentioned below are unpatentable under Section 32 of the Patent Law.
4. The application is unpatentable under Section 36 (4) of the Patent Law because the Detailed Description of the Invention is defective in the following respect.

REMARKS

Re: Reason 1

References Cited:

- FILED
12-05-02
1. J. Mol. Biol. (1986) Vol. 187, No. 2, pp. 197-212
 2. Nature (1997) Vol. 389, No. 6646, pp. 40-46
 3. Proc. Natl. Acad. Sci. USA (1992) Vol. 89, No. 14, pp. 6232-6236
 4. Proc. Natl. Acad. Sci. USA (1992) Vol. 89, No. 15, pp. 6861-6865

References 1 and 2 are applicable to claims 1-7 and 11.

References 1 and 2 disclose Cre recombinases derived from the bacteriophage P1.

The invention of claim 1 differs from References 1 and 2 in the following respect:

- (1) Unlike Reference 1, claim 1 of this application recites that the recombinase is modified to have a high efficiency of expression in mammals.

This difference will now be discussed.

At the time the application was filed, it was well-known art that when a certain gene is to be expressed in a host with a higher efficiency of expression, the frequency of use of a codon in the host is considered and a gene modified with a codon with a high efficiency of expression. Taking this into account, it is easily conceivable by a skilled person to apply the well-known art to References 1 and 2 and to modify the bacteriophage P1-derived Cre recombinase with a frequently used codon (having a high efficiency of expression), which corresponds to the same amino acid and is considered to have a high efficiency of expression in mammals, thereby to efficiently express the Cre recombinase in mammals.

The inventions of claims 2-7, too, are obvious over the citations.

References 1-4 are applicable to claims 12-14.

References 3 and 4 disclose Cre/loxP recombinase systems derived from the bacteriophage P1.

As regards claim 12, it is obvious to a person skilled in the art to apply the well-known art to References 1 and 2 and to use a Cre recombinase modified to efficiently express a bacteriophage P1-derived Cre recombinase in mammals, as the bacteriophage P1-derived Cre recombinase used in the methods of References 3 and 4.

The inventions of claims 13 and 14, too, are obvious over the citations.

Re: Reason 2

The invention of claim 20 relates to a method of medical treatment for humans, and is not an industrially applicable invention.

Re: Reason 3

The inventions of claims 8-10, 15 and 17-19 include a human body or a matter separated from a human body as an indispensable structural element, and are considered to be "inventions liable to contravene public order, morality or public health."

Re: Reason 4

The "Detailed Description of the Invention" fails to describe a specific example of production of a transgenic pig recited in claim 16. Therefore, the specification is not drafted clearly and sufficiently for a person skilled in the art to carry out the invention.

[Examiner, N. Honma, the 4th Division of Patent Examination
(Biotechnology), Tel. 03(3581)1101, Extension 3488, Fax No. 03(3501)0491]

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Prior Art Search Report

Searched Field: DB Name, SwissProt/PIR/GeneSeq
Genbank/EMBL/DDBJ/GeneSeq

Prior Art Document(s):

Jpn. Pat. Appln. KOKAI Publication No. 9-206082
Jpn. Pat. Appln. KOKAI Publication No. 10-113174
Jpn. Pat. Appln. KOKAI Publication No. 11-332579

[The result of this prior art search does not constitute the reasons for rejection.]